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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/363,728	07/29/1999	SARATH KRISHNASWAMY	6401.US.01	8480
7590 05/19/2005 DAVID L WEINSTEIN COUNSEL ABBOTT LABORATORIES DEPT 377 AP6D/2 100 ABBOTT PARK ROAD ABBOTT PARK, IL 600646050			EXAMINER LE, UYEN CHAU N	
			ART UNIT 2876	PAPER NUMBER

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/363,728

Applicant(s)

KRISHNASWAMY ET AL.

Examiner

Uyen-Chau N. Le

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2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *BPAI Decision*

1. In light of the BPAI decision, see pages 4-7 of the BPAI decision filed 29 March 2005, with respect to the rejection(s) of claim(s) 1-2 and 5-6 under 35 USC 103 rejection, the examiner withdraws the previous rejection. However, upon further consideration, a new ground(s) of rejection is made in view of the newly cited references to Karkar et al.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al (US 5,507,288) in view of Karkar et al (US 5,066,859).

Re claim 1, Böcker et al shows and discloses hand-held analytic test instrument comprising a housing, a barcode reader 28, a port 17, a display 21, a user interface 20 (e.g., on/off button) capable of activating the barcode reader. The barcode reader 28 is disposed in the housing for scanning a barcode associated with a test strip 13. The port 17 is disposed in the housing for receiving the test strip 13. The instrument also comprising an electronic circuit that in electrical communication with the port 17 for processing an analytic signal received from the test strip 13 and generating analytic data there-from. The display 21 is in electrical communication with the circuit for displaying certain analytical data. The instrument further comprises a connector in electrical communication with the circuitry and electrically connectable to a host computer via a data communications network, wherein the circuitry automatically uploads the analytical data to the host computer upon connection thereto. (See Figs. 1&2; col. 5, line 35 - col. 6, line 60; and col. 8, lines 25-28).

Böcker et al fails to teach or fairly suggest a numeric keypad for selecting test or menu modes, editing entries, terminating entries.

Karkar et al teaches a blood analyzing device including display 16 and keypad 18; pH and temperature values are entered by the user through the keypad 18, thus keypad 18 must be a numeric keypad (fig. 1; col. 10, line 68 through col. 11, line2).

It would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to incorporate the conventional keypad as taught by Karkar et al into the teachings of Böcker et al in order to provide the user with a more flexibility in selecting which test to perform and in inputting the necessary data. Furthermore, such modification would have

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been an obvious extension as taught by Böcker et al, well within the ordinary skill in the art, and therefore an obvious expedient.

5. Claims 2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al in view of Cargin, Jr. et al (US 5,602,456 - cited by the applicant) and Karkar et al. The teachings of Böcker et al as modified by Karkar et al have been discussed above.

Re claims 2 and 5-6, Böcker et al shows and discloses hand-held analytic test instrument comprising a housing, a port 17, a display 21, a battery compartment; a barcode reader 28 disposed in the housing; and a user interface 20 for activating the barcode reader 28. The port 17 is disposed in the housing for receiving the test strip 13. The instrument also comprising an electronic circuit that in electrical communication with the port 17 for processing an analytic signal received from the test strip 13 and generating analytic data there-from. The display 21 is in electrical communication with the circuit for displaying certain analytical data. The instrument further comprises a connector in electrical communication with the circuitry and electrically connectable to a power source. The battery compartment is formed in the housing and inherently comprising a pair of electrical contacts for providing power from a battery to the electronic circuitry and a rechargeable battery disposed in a battery holder. (See Figs. 1&2; and col. 5, line 35 - col. 7, line 8).

Böcker et al fails to disclose or fairly suggest that the battery compartment also comprising a pair of recharge contacts; a bus bar and a user interface capable of allowing an operator to enter data, wherein the bus bar is disposed on the battery holder and in electrical communication with the pair of recharge contacts for recharging the batter when the instrument is connected to the power source.

Cargin, Jr. et al teaches that the battery compartment comprising those contacts 34, 35; a bus bar 32 for recharging the battery directly without removing the battery out of the compartment 29, and for preventing the inadvertent and possibly hazardous application of recharging electrical power to non-chargeable batteries (col. 12, lines 42-46); and a user interface, which is keypad 14 having a plurality of keys 56 (fig. 1; col. 10, lines 1-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Cargin Jr. et al into the teachings of Böcker et al due to the fast, easy, and convenience way of recharging the battery directly without removing the battery out of the compartment. Furthermore, such modification would have provided Böcker et al with a more user-friendly system, wherein the user can enter the required data manually via the keypad. Accordingly, such modification would have been an obvious extension as taught by Böcker et al, well within ordinary skill in the art, and therefore an obvious expedient.

Böcker et al as modified by Cargin Jr. et al is silent with respect to a numeric keypad for selecting test or menu modes, editing entries, terminating entries.

Karkar et al teaches a blood analyzing device including display 16 and keypad 18; pH and temperature values are entered by the user through the keypad 18, thus keypad 18 must be a numeric keypad (fig. 1; col. 10, line 68 through col. 11, line2).

It would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to incorporate the conventional keypad as taught by Karkar et al into the teachings of Böcker et al/Cargin Jr. et al in order to provide the user with a more flexibility in selecting which test to perform and in inputting the necessary data. Furthermore, such

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modification would have been an obvious extension as taught by Böcker et al/Cargin Jr. et al, well within the ordinary skill in the art, and therefore an obvious expedient.

6. Claim 4 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 5,307,263) in view of Cheung et al. The teachings of Cheung et al have been discussed above.

Re claim 4, Brown teaches the method of managing data for a plurality of test instrument connected to a data communication network comprising step of detecting via a host computer the connection of each instrument to the data communication network; uploading data receiving from each instrument to the host computer; processing the uploaded data on the host computer for operator review; and downloading configuration data from the host computer to each test instrument (figs. 1&2; col. 8, line 14 through col. 15, line 44).

Brown fails to teach or fairly suggest that each instrument including a test strip port, which accepts test strip for determining the level of analyte in a sample taken from a patient.

Cheung et al teaches the above limitation with a measurement 10 having a slot for accepting test strip 16 (fig. 2; col. 10, lines 24+).

It would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to incorporate the teachings of Cheung et al into the teachings of Brown in order to provide Brown with a high-tech system, wherein the reading results (i.e., level of analyte) of each analyte test can be directly transmitted to the host computer and the instruction for setting up and controlling of each analyte test can be received directly from the host computer. Furthermore, such modification would have provided Brown with a more compact system, wherein the data communication network system and the analyte test apparatus are in the same unit/instrument. Accordingly, such modification would have been an obvious extension as

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taught by Brown to provide Brown with a more user-friendly system, wherein the user can have the analyte test result readily, well within ordinary skill in the art, and therefore an obvious expedient.

*Allowable Subject Matter*

7. Claim 3 is allowed.

8. The following is an examiner's statement of reasons for allowance:

The prior art of records to Böcker et al, Karkar et al, Cargin Jr. et al, Koenck, Davis '943, Davis '966, Cheung et al, Brown and all other cited references, taken alone or in combination, fails to teach or fairly suggest the specific structure or the method of a hand-held analyte test instrument comprising, among other things, a switch in electrical communication with the connector, a first data port in electrical communication with the switch and being electrically connectable to a computer, a second data port in electrical communication with the switch and being electrically connectable to a peripheral device, and a control mechanism for controlling the switch to selectively pass the analyte data to the computer via the first data port or to the peripheral device via the second data port as set forth in the claims combination.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The patents to Beckers (US 5019974 A); Simons et al (US 5871494 A); Simons et al (US 5971941 A); Douglas et al (US 6106780 A); Heinonen et al (US 6295506 B1); Buechler et al (US 6830731 B1) are cited as of interest and illustrate a similar structure to an analyte test instrument system including data management system.

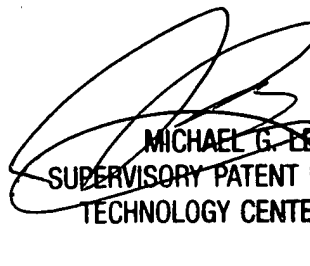
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Uyen-Chau N. Le whose telephone number is 571-272-2397. The examiner can normally be reached on Mon-Fri. 5:30AM-2:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL G. LEE can be reached on 571-272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Uyen-Chau N. Le  
May 17, 2005



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